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<b>13. SUPPLEMENTARY NOTES</b>				
<b>14. ABSTRACT</b> This study is a follow up to two projects, funded by the Office of Naval Research, which demonstrated that Virtual Reality Exposure Therapy was safe and effective for the treatment of Post Traumatic Stress Disorder in Service Members who served in Iraq or Afghanistan, and that it worked better than treatment as usual. In this study, we are attempting to discover if the Virtual Reality is actually the active component of the treatment. Participants with PTSD are randomized to receive the same treatment that was successful in the previous projects, or the same treatment in which a simple, still computer image replaces the Virtual Reality. Progress on the grant was initially delayed pending secondary review from the Department of the Navy, and approval to recruit from TATRC. During the intervening period, we performed clinical cases using the VR to train therapists, registered the project with clinicaltrials.gov, upgrade our software, and establishing recruiting pools. Several volunteer therapists and technicians were recruited to assist the project. We received approval in September 2009, and are now running with 8 patients enrolled in the first 10 week block of treatment. We have also gone through annual review for our IRB, and have been approved for our second year. We anticipate our post treatment assessments being completed in early November 2009.				
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**INTRODUCTION:** This study is intended to determine if the Virtual Reality (VR) simulator used in Virtual Reality Exposure Therapy (VRET) is the active component when using the technique to treat combat-related PTSD. It is a multi-site, randomized, single blind comparison of VRET versus a control condition that uses all the same components of therapy, except that a single, still computer image is used to focus a subjects attention rather than having him/her use a full, VR simulator. The VRET is conducted in the same fashion as has been previously used to treat combat PTSD, with up to twice a week therapy for ten weeks. Subjects are assessed by independent, blinded raters before and after treatment, and three months later to determine long-term follow up. Success is determined by showing improvements on the Clinician Administered PTSD Scale (CAPS). The study was designed to complete treatment of 80 subjects (40 active and 40 controls) over the course of 4 years. A fifty percent dropout rate was anticipated. The study was to be completed at two military facilities, Naval Medical Center San Diego, and Marine Corps Base Camp Pendleton. Each of those sites contains several, smaller clinics. The first stage of the project was to recruit and train research therapists, and research assistants, to obtain IRB approval to conduct the study, and to set up measures to ensure and monitor protocol adherence and progress. This includes both weekly research meetings, and annual safety and efficacy review in which data is compiled each year to ensure that subjects in either the active or the control condition are not receiving care that is anything less than ideal. Because of funding cuts to the original budget, the study is dependent on including volunteer research therapists and research assistants who work on the project without cost to the grant.

## **BODY:**

The study has recruited and trained research personnel, obtained IRB approval, set up review and safety procedures, and started recruiting, assessing, and treating research subjects.

Currently, we have five therapists actively treating patients, and five simulators where treatment can be conducted. With this number, we are currently able to treat up to 9 patients at a time. We need to maintain 4 subjects in treatment at all times to maintain project goals. As might be expected from working with volunteer, active duty therapists, there has been some personnel turnover as therapists move between commands and compete with other obligations. Therapists must have prior experience in traditional exposure therapy, complete IRB research requirements, and complete a supervised “training case” in VRET before we would include data from subjects treated by that provider. All research therapists also participate in a weekly supervision and monitoring meeting (in person or by video conference) in which protocol adherence is maintained. We have conducted several training seminars for military therapists, and at various times, had nine therapists formally credentialed for the project.

So far, fifty subjects have given informed consent to be assessed for the study. Eight of these did not meet study criteria and were excluded. Four subjects were treated by a first-time therapist, and therefore were considered “training cases”, with data excluded from analysis. Six subjects elected not to enter treatment (dropped out prior to randomization). Four subjects (two active, and two controls) dropped from the study after enrollment. One of these four was due to an adverse event (becoming suicidal during treatment). The other three electively left the program. Twenty-four subjects completed treatment and a post-treatment assessment. Five subjects are currently in treatment. Ten subjects have contributed long-term (3 month +) follow up data. Recruitment is ongoing.

We completed preliminary safety and efficacy review in preparation for the annual IRB review. At that point, 20 subjects had completed treatment. No statistically significant differences at this point between those in the Active (virtual reality) and Control conditions. Both groups of subjects experienced statistically and clinically significant improvements over the course of treatment. Average improvement was 47% (39 points) in controls, and 42% (27 points) in the Active VR condition. At this point, eight subjects had also completed long term

follow up. Only 1 of 4 subjects in the control condition had maintained improvements at three months, whereas 2 of 4 active VR subjects have maintained improvements. This was not a statistically significant difference. Interestingly, none of the patients who failed to respond to research treatment (either active or control) have shown improvement in the 3 month interval, despite having engaged in other modes of treatment during that period.

Weekly supervision meetings for protocol adherence and safety monitoring are ongoing according to plan.

There has been one presentation on the project, “Virtual Reality for Combat PTSD” at the San Diego 2010 Institute for Defense and Government Advancement Battlefield Healthcare summit, Sept 22, 2010. There have, however, been no abstracts or papers yet produced from this project.

Safety and IRB review has been completed for the year, and we intend to continue on with our current methods. One of our volunteer research psychologists has been reassigned to a new military facility. Materials have been submitted to add this location, U.S. Fleet Activities Base Sasebo, Japan, as a third research site for the project. Logistics of conducting supervision and assessments at this site have been established. Once a letter of support has been received by the facility, we will request approval from USAMRAA to add an additional research site. Dr. O’Neese will serve as site primary investigator for that location once it is approved.

Only one item from the statement of work is relevant to the current study period:

Task 2: Month 7 to month 42: Recruit and enroll approximately 8 patients per treatment period, with the expectation that 4 of these will enter VRET or CET treatment phases, and be eligible for intention to treat analysis.

In the previous fiscal year, we started this phase six months late. We continue to be approximately six months behind our overall goals in terms of recruiting and treatment subjects in the protocol. Our current enrollment and treatment rate slightly exceeds the 4 subjects at a time, anticipated, but not at great enough a rate to fully make up for the initial starting delay.

## **KEY RESEARCH ACCOMPLISHMENTS:**

- Key personnel and procedures in place to conduct and test Virtual Reality Exposure Therapy versus the control condition
- Annual safety and efficacy review was conducted, which showed that subjects are improving in both treatments. So far, there are no statistically significant differences between how subjects are performing in the active and control groups.
- All elements in place to continue to treat subjects and gather data for the following year.

## **REPORTABLE OUTCOMES:**

There has been one presentation on the project, “Virtual Reality for Combat PTSD” at the San Diego 2010 Institute for Defense and Government Advancement Battlefield Healthcare summit, Sept 22, 2010. Audience members included the Surgeon General of the Air Force Reserve, the commander of Madigan Army Medical Center, and other key military decision makers. There have, however, been no abstracts or papers yet produced from this project.

This project has been highlighted as part of several VIP visits to Naval Medical Center San Diego, and has become one of the standard highlights for VIP tours of the medical center. This included presentations to the new commanding admiral for NMCS and Navy Medicine West, Rear Admiral Faison, and the new Executive Steering Committee for Navy Medicine West.

Five Virtual Reality simulators have been established in military mental health clinics, and a sixth is being built currently. Twenty nine therapists from military clinics have been given basic instruction in how to conduct virtual reality therapy, and nine therapists have completed training to the point that they could function as therapists on the grant.

**CONCLUSION:** Preliminary findings confirm previous reports that VRET is a safe and effective treatment for combat-related PTSD. So far, however, we do not have sufficient evidence to say that the virtual reality simulator actually improves outcomes when compared to the same techniques used without benefit of the advanced technology.

**REFERENCES:** Not applicable.

**APPENDICES:** None

**SUPPORTING DATA:** Not applicable.